

Message Text

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PAGE 01 STATE 174532
ORIGIN HEW-06

INFO OCT-01 ARA-14 EUR-12 ISO-00 OES-09 MED-05 /047 R

DRAFTED BY DHEW/FDA: JRWEINROTH, MD:VO
APPROVED BY OES/ENP/EN: WJWALSH, III
EUR/S A /OIH: MKEFAUVER
ARA/AND/V SERGEANT(INFO)
ARA/CAR :DPIERCE(INFO)
EUR/NE:WNEWLIN(INFO)

-----094913 120046Z /70

P 111950Z JUL 78
FM SECSTATE WASHDC
TO AMEMBASSY CARACAS PRIORITY
AMCONSUL CURACAO PRIORITY
AMEMBASSY BRUSSELS PRIORITY

UNCLAS STATE 174532

E.O. 11652: N/A

TAGS: OGEN, ETRD, EIND, TBIO, VE, NA, BE

SUBJECT:FDA ADVISORY - FALSE POSITIVE REACTIONS ASSOCIATED
WITH USE OF IN-VITRO DIAGNOSTIC PRODUCT

1. FDA ADVISES OF THE FOLLOWING FIRM INITIATED RECALL:
PRODUCT INVOLVED - THE PRODUCT INVOLVED IS BOVINE ALBUMIN
22 PERCENT SOLUTION PACKAGED I; SEVERAL DIFFERENT CON-
FIGURATIONS. LIST NUMBER 022-143 IS A 10 ML SINGLE PACK;
LIST NUMBER 011-144 IS A 10 ML SIX PACK; LIST NUMBER 022-
147 IS A 50 ML SINGLE PACK.

2. PRODUCT IDENTIFICATION - PRODUCTS ARE LABELED IN PART
AS FOLLOWS: 10 ML VIALS ARE LABELED IN PARTS '10 ML
BOVINE ALBUMIN 22 PERCENT SOLUTION (V) PRESERVATION;
SODIUM AZIDE, 0.1 PERCENT....FOR INVITRO DIAGDOSTIC USE...
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LOT NO....EXP. DATE ... HYLAND DIV. TRAVENOL LABORATORIES,
INC., COSTA MESA, CALIFORNIA...."

. 10 ML VIALS ARE PACKAGED SINGLY ,; PAPERBOARD CARTONS
LABELED IN PART: "10 ML LIST NO. 022-143 BOVINE ALBUMIN
22 PERCENT SOLUTION (W/V) FOR USE IN IMMUNOHEMATOLOGIC
TESTING HYLAND DIV. TRAV-NOL LAB..... SEE ENCLOSED

DIRECTIONS FOR USE.....,

4. 10 ML VIALS ARE PACKAGED IN UNITS OF SIX IN A PAPER-BOARD CARTON LABELED IN PART "SIX 10 ML VIALS LIST NO. 022-144 BOVINE ALBUMIN 22 PERCENT SOLUTION (N/V) FOR USE IN IMMUNOHEMATOLOGIC TESTING HYLAND DIVISION TRAVENOL LABORATORIES...."

5. 50 ML VIALS ARE LABELED IN PART: "50 ML BOVINE ALBUMIN 22 PERCENT SOLUTION (W/V)....FOR IN VITRO DIAGNOSTIC USE... HYLAND DIV. TRAVENOL LABORATORIES..." PAPERBOARD PACKAGES READ IN PART: "50 ML LIST NO. X 022-147 BOVINE ALBUMIN 22 PERCENT SOLUTION..."

6. THE PACKAGE INSERT FOR THE ITEMS READS IN PART:
"HYLAND BOVINE ALBUMIN 22 PERCENT SOLUTION...SUMMARY... REAGENT...PROCEDURE...LIMITATION...HYLAND DIV. TRAVENOL LABORATORIES... THE LOT NUMBERS INVOLVED ARE:
0992D001AA (10 ML SINGLE PACK)
0992D001AB (10 ML SINGLE PACK)
0992D001BA (50 ML SINGLE PACK)

7. MANUFACTURER/RECALLING FIRM:
HYLAND DIV. TRAVENOL LABORATORIES
3300 HYLAND AVE.
COSTA MESA, CALIFORNIA
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PRODUCT WAS FILLED AND LABELED BY HYLAND'S ROUND LAKE, ILLINOIS PLANT.

8. REASON FOR RECALL: THE FIRM IS RECALLING THE ITEM BECAUSE WHEN VIEWED WITH A MICROSCOPE FALSE POSITIVE REACTIONS MAY OCCUR. THE FIRM LEARNED OF THE PROBLEM DUE TO SEVERAL TRADE COMPLAINTS WHICH WERE VERIFIED BY EXAMINATION OF RETURNED STOCK AND RESERVE SAMPLES. RECALL WAS BEGUN ON 10-13-77 BY LETTER. NO INJURIES OR DEATHS ARE ASSOCIATED WITH THE PRODUCT.

9. POSTS ARE REQUESTED TO CONTACT FOREIGN CONSIGNEES TO DETERMINE IF THEY HAVE BEEN ADVISED BY HYLAND DIV. TRAVENOL LABORATORIES OF RECALL AND DISPOSITION OF PRODUCT. ANY QUESTIONS CONSIGNEES MAY HAVE SHOULD BE DIRECTED TO FIRM.

10. FOREIGN CONSIGNEES PROVIDED TO FDA BY FIRM ARE:

LABORATORIES BAXTER C.A.,CARACAS, VENEZUELA

DOUBER AGENCIES N.V., CURACAO, NETHERLANDS ANTILLES

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TRAVENOL LABS, BELGIUM CHRISTOPHER

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NNN

Message Attributes

Automatic Decaptioning: X
Capture Date: 01 jan 1994
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: RECALLS, FOOD & DRUG REGULATIONS
Control Number: n/a
Copy: SINGLE
Draft Date: 11 jul 1978
Decaption Date: 01 jan 1960
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01 jan 1960
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1978STATE174532
Document Source: CORE
Document Unique ID: 00
Drafter: JRWEINROTH, MD:VO
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Expiration:
Film Number: D780284-0626
Format: TEL
From: STATE
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1978/newtext/t19780773/aaaacjks.tel
Line Count: 118
Litigation Code IDs:
Litigation Codes:
Litigation History:
Locator: TEXT ON-LINE, ON MICROFILM
Message ID: ce864977-c288-dd11-92da-001cc4696bcc
Office: ORIGIN HEW
Original Classification: UNCLASSIFIED
Original Handling Restrictions: n/a
Original Previous Classification: n/a
Original Previous Handling Restrictions: n/a
Page Count: 3
Previous Channel Indicators: n/a
Previous Classification: n/a
Previous Handling Restrictions: n/a
Reference: n/a
Retention: 0
Review Action: RELEASED, APPROVED
Review Content Flags:
Review Date: 29 mar 2005
Review Event:
Review Exemptions: n/a
Review Media Identifier:
Review Release Date: N/A
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
SAS ID: 2048118
Secure: OPEN
Status: NATIVE
Subject: FDA ADVISORY - FALSE POSITIVE REACTIONS ASSOCIATED W'ITH USE OF IN-VITRO DIAGNOSTIC PRODUCT
TAGS: OGEN, ETRD, EIND, TBIO, VE, NA, BE
To: CARACAS CURACAO MULTIPLE
Type: TE
vdkgvwkey: odb://SAS/SAS.dbo.SAS_Docs/ce864977-c288-dd11-92da-001cc4696bcc
Review Markings:
Sheryl P. Walter
Declassified/Released
US Department of State
EO Systematic Review
20 Mar 2014
Markings: Sheryl P. Walter Declassified/Released US Department of State EO Systematic Review 20 Mar 2014